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Dated: 3/29/15

Signature:

*Shawn P. Foley*  
(Shawn P. Foley)

Docket No.: LOREAL 3.0-039  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Fares et al.

Application No.: 10/646,300

Filed: August 22, 2003

For: COMPOSITIONS CONTAINING TOPICAL  
ACTIVE AGENTS AND PENTYLENE  
GLYCOL

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: Group Art Unit: 1617  
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: Examiner: Williams,  
Leonard M.  
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

I, Hani Fares, do declare as follows:

I received a Doctor of Philosophy degree in  
Pharmaceutics from Rutgers University in 1997.

I have more than 15 years of experience in the fields  
of cosmetics and dermatology, particularly from the standpoint  
of cosmetic and dermatological formulations.

I have been employed by Loreal, S.A. for more than 3  
years, and have held the title of Manager since 2005.

I am a named co-inventor of the captioned patent  
application.

I have reviewed the Office Communication mailed  
January 11, 2005, and the four publications cited therein,  
namely U.S. Patents 6,113,888 to Castro, et al. ("Castro"); U.S.  
Patent 4,552,872 to Cooper, et al. ("Cooper"); U.S. Patent  
6,075,056 to Quigley, et al. ("Quigley"); and U.S. Patent  
6,274,124 to Vollhardt ("Vollhardt").

I disagree with the determination reached by the Examiner that claims of the patent application would have been obvious over *Castro*, in view of *Cooper* and *Quigley*, and further in view of *Vollhardt*. In my opinion, no one claim of this patent application would have been obvious in view of the collective teachings of these four patents.

In my opinion, the teachings of *Cooper* would not have motivated a person skilled in the art to include pentylene glycol in a topical cosmetic or dermatological composition with a reasonable expectation that it would have enhanced penetration and uptake of a cosmetic or dermatological active agent. Although not explicit, *Cooper's* limitation to C3-C4 diols would have discouraged use of a C5 diol. My co-inventors and I, however, proceeded contrary to *Cooper's* teachings.


The invention disclosed in *Vollhardt* is directed to a method for imparting water resistance or to improving water resistance of a cosmetic or dermatological formulation containing a sunscreen agent or other active agent, by adding a water resistance enhancing effective amount of 1,2-pentanediol to an otherwise cosmetic or dermatological formulation that contains at least one cosmetic and/or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier, for topical application to the skin of humans. On Column 3, lines 10-14, *Vollhardt* teaches that with respect to formulations comprising cosmetic and/or dermatological active agent(s) other than UV protectants, the term "water resistance" refers to the activity or effect over time of the respective agent of a formulation subjected (after application to the skin) to contact with water. When read in the context of the entire patent disclosure, including the background section, I take this statement to mean that when applied to human skin in a formulation containing 1,2-pentanediol, the active agent is not as easily washed off, and has a higher retention on human skin

upon contact with water or other aqueous solutions, than it would have in the absence of pentylene glycol.

We sought to increase solubility of hydrocortisone and the rate and/or extent of penetration through the skin barrier, and in so doing, unexpectedly discovered that hydrocortisone is more soluble in pentylene glycol than in other diols. The claimed invention achieves unexpected results, namely greater aesthetic appeal, less tackiness, and greater penetration and bioavailability of hydrocortisone, compared to other commercial hydrocortisone topical formulations. Increasing water resistance and retention on the skin, which were Vollhardt's objectives, are completely different and even opposite the properties we were seeking, namely increased solubility, penetrability and bioavailability.

I declare under penalty of perjury that the foregoing is true and correct.

Date: March 28, 2005

  
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HANI FARES